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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,026	07/06/2001	Andre Stamm	107664.115US3	7379

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EXAMINER

SHEIKH, HUMERA N

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 03/14/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/899,026

Applicant(s)

STAMM ET AL.

Examiner

Humera N. Sheikh

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2002 (paper no.13).
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 91-161 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 91-161 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/005,128.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### **Status of the Application**

Acknowledgement is made of the receipt of the request for extension of time (2 months), the Amendment and the Terminal Disclaimer, all filed 11/06/02.

Claims 91-161 are pending. Claims 35-90 have been cancelled by virtue of the amendment. Claims 91-161 are rejected.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 91, 99, 116, 119, 121, 122 and 124 are rejected under 35 U.S.C. 102(b) as being anticipated by Boyer (US Pat. No. 4, 800,079).**

Boyer discloses a fenofibrate composition comprising granules, wherein the granules comprise an inert core with hydrosoluble carrier particles (lactose), a hydrophilic polymer (polyvinylpyrrolidone) and a fenofibrate microparticle layer, wherein the fenofibrate particles have a particle size of not greater than 30 microns (see reference columns 2-4).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 92-98, 100-115, 117, 118, 120, 123 and 125-161 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyer (US Pat. No. 4, 800,079) in view of Curtet *et al.* (US Pat. No. 4, 895,726).**

Boyer teaches a fenofibrate composition comprising granules, wherein the granules comprise an inert core with hydrosoluble carrier particles (lactose), a hydrophilic polymer (polyvinylpyrrolidone) and a fenofibrate microparticle layer, wherein the fenofibrate particles have a particle size of not greater than 30 microns (see reference columns 2-4).

Boyer does not explicitly teach all the exact instantly claimed weight ratios and percentages. It would have been obvious to one of ordinary skill in the art at the time the invention was made that suitable ratios and percentages could be determined through routine or manipulative experimentation. In addition, no criticality is seen in the instantly claimed weight ratios and percentages since Boyer teaches the same claimed ingredients in similar amounts and therefore the properties would also be the same.

Boyer's patent is deficient only in the sense that it does not explicitly teach a surfactant in the fenofibrate composition.

**Curtet** et al. teach a fenofibrate composition comprising micronized fenofibrate in combination with a surfactant (sodium-lauryl sulfate) (see reference columns 1-6).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Curtet within the teachings of Boyer because Curtet explicitly teaches a fenofibrate composition co-micronized with a surfactant -sodium lauryl-sulfate, which makes it possible to improve the absorption and consequently the bioavailability of the fenofibrate to a greater extent. The expected result would be an improved and highly effective fenofibrate composition.

### ***Response to Arguments***

The examiner and her primary examiner had made suggestions in the interview of 10/17/02 to provide a comparison of the dissolution rates of Boyer's product and the instant product using a similar method, if possible. The applicant has not provided this information. The instant invention remains unpatentable over the prior art and therefore the rejection of claims 91-161 is maintained.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

### **Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (703) 308-4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

*hns*

March 12, 2003

THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
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